

PRELIMINARY AMENDMENT

Serial Number: Unknown

Filing Date: Herewith

Title: THERAPEUTIC INHIBITOR OF VASCULAR SMOOTH MUSCLE CELLS

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In the Claims

Please [✓]cancel claims 1-20 without prejudice.

Please [✓]add the following new claims:

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21. (New) A therapeutic method, comprising treating procedural vascular trauma associated with placement of a device in a vessel by administering to a mammal an amount of a cytostatic agent that does not exhibit substantial cytotoxicity, which agent and amount are selected to allow for vascular repair and extracellular matrix production in the traumatized vessel.
22. (New) A method to inhibit or treat procedural vascular trauma associated with placement of a device in a vessel in a mammal, comprising:
- a) providing a cytostatic agent in an selected amount, wherein the selected amount allows for repair and extracellular matrix production in mammalian vascular smooth muscle cells, and wherein the cytostatic agent does not exhibit substantial cytotoxicity; and
 - b) administering the cytostatic agent to a mammal subjected to vascular trauma in an amount which allows for vascular repair and extracellular matrix production in the traumatized vessel and inhibits or treats procedural vascular trauma.
23. (New) A therapeutic method, comprising treating procedural vascular trauma associated with placement of a device in a vessel by administering to a mammal a cytostatic agent that does not exhibit substantial cytotoxicity in an amount which has a minimal effect on protein synthesis and allows for vascular repair and extracellular matrix production in the traumatized vessel
24. (New) The method of claim 21, 22 or 23 wherein the vessel is subjected to [✓]angioplasty, placement of a stent or grafting.

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25. (New) The method of claim 21, 22 or 23 wherein the agent inhibits microtubules.
26. (New) The method of claim 21, 22 or 23 wherein the agent inhibits microfilaments.
27. (New) The method of claim 21, 22 or 23 wherein the agent inhibits actin polymerization.
28. (New) The method of claim 21, 22 or 23 wherein the agent is a cytochalasin or an analog thereof.
29. (New) The method of claim 21, 22 or 23 wherein a cytoskeletal inhibitor is administered.
30. (New) The method of claim 21, 22 or 23 wherein the administration is local.
31. (New) The method of claim 21, 22 or 23 wherein the administration is systemic.
32. (New) The method of claim 21, 22 or 23 wherein the administration is before, during or after the trauma.
33. (New) The method of claim 21, 22 or 23 wherein the administration is during the trauma.
34. (New) The method of claim 21, 22 or 23 wherein the administration is accomplished by the device.

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35. (New) The method of claim[✓] 21, 22 or 23 wherein the administration is accomplished by a catheter.
36. (New) The method of claim[✓] 21, 22 or 23 wherein the amount is effective to inhibit migration of vascular smooth muscle cells.
37. (New) The method of claim[✓] 21, 22 or 23 wherein the agent is administered in a sustained release dosage form.
38. (New) The method of claim[✓] 21, 22 or 23 wherein the agent is administered in a polymeric carrier.
39. (New) The method of claim[✓] 37 wherein the sustained release dosage form is biodegradable.
40. (New) The method of claim[✓] 21, 22 or 23 wherein the agent is administered in a sustained release dosage form and delivered by the device.
41. (New) The method of claim[✓] 37 wherein the sustained release form comprises a binding peptide or protein which specifically binds to smooth muscle cells, stromal cells or extracellular matrix surrounding smooth muscle cells.
42. (New) The method of claim[✓] 37 wherein the sustained release dosage form comprises microparticles or nanoparticles.
43. (New) The method of claim[✓] 37 wherein the sustained release dosage form comprises a polymer derived from the condensation of alpha-hydroxycarboxylic acids and related lactones.

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44. (New) The method of claim 43 wherein the polymer is selected from the group consisting of a polylactide, a polyglycolide, and a copolymer of lactide and glycolide subunits.
45. (New) The method of claim 44 wherein the polymer is poly(lactide co-glycolide).
46. (New) The method of claim 21, 22 or 23 wherein the agent releases nitric oxide.
47. (New) The method of claim 21, 22 or 23 wherein the agent inhibits the proliferation of smooth muscle cells.
48. (New) A method to screen for an agent to inhibit or treat procedural vascular trauma, comprising:
 - a) selecting a cytostatic agent that does not exhibit substantial cytotoxicity on mammalian vascular smooth muscle cells; and
 - b) identifying an amount of the cytostatic agent which allows for extracellular matrix production in mammalian vascular smooth muscle cells.
49. (New) The method of claim 21, 22 or 48 wherein the amount of the agent has a minimal effect on protein synthesis.